K040388
1 of 2

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

MAY 17 2004

Section H – 510(K) Summary

Date Summary Was Prepared: February 12, 2004

Submitter's Information:
The Kendall Company
Division of Tyco Healthcare Group, LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000
Fax: 508-261-8461

Contact:
Jim Welsh
Director, Regulatory Affairs
The Kendall Company
Division of Tyco Healthcare Group, LP
Telephone: 508-261-8532
Fax: 508-261-8461

Device Trade Name: Next Generation Salem Sump

Device Common Name: Tube, double lumen for intestinal decompression and/or intubation

Classification Panel: Gastroenterology

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Kendall Salem Sump (naso gastric) tube with Anti-Reflux Valve, 510(k) number K935781/A, cleared on January 10, 1995.
- Bard (Davol) NasoGastric Sump tube with PreVent Anti-Reflux filter, 510(k) number K960176, cleared on July 24, 1996.
- ICU Medical Lopez Valve, 510(k) number K915171, cleared February 7, 1992
- ICU Medical Lopez Valve with NG tube, 510(k) number K921104, cleared on October 26, 1992.

K040388
2 of 2

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
Next Generation Salem Sump

Section H – 510(K) Summary

Device Description: The Next Generation Salem Sump is a dual lumen Naso Gastric tube with a multiport connector/valve to facilitate switching among the various function of the device.

Intended Use: The Next Generation Salem Sump is intended for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication, during the time period that gastric decompression is required.

Product Comparison: The proposed device has the same technological characteristics as the predicate devices. Both the proposed device and the predicate devices are intended to be used for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication. The construction of both the proposed and predicate devices is based upon a dual lumen PVC nasogastric tube, with external connection ports suitable for connection with commonly available devices such as vacuum adaptors, feeding sets, and irrigation syringes. Both the proposed device and the predicate devices are equipped with a mechanism to prevent gastric reflux from the vent lumen of the device.

Nonclinical Testing: Testing was conducted to demonstrate that the design of the proposed device was equivalent to the predicate devices, and/or met the industry accepted criteria for such devices, as defined in EN1615:2000.

James Welsh

Jim Welsh
Director, Regulatory Affairs
Tyco Healthcare/Kendall

2-12-04

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

Mr. James Welsh
Director, Regulatory Affairs
The Kendall Company
Tyco Healthcare Group, LP
15 Hampshire Street
MANSFIELD MA 02048

Re: K040388
Trade/Device Name: Next Generation Salem Sump
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 FEG
Dated: February 12, 2004
Received: February 17, 2004

Dear Mr. Welsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040388

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
Next Generation Salem Sump

Appendix 1

Indications for Use Statement

Device Name:

Next Generation Salem Sump

Indications for Use:

The Next Generation Salem Sump is intended for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication, during the time period that gastric decompression is required.

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040388